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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	CASE NO.: 2:16-cv-02525-MMD-NJK (consolidated) CASE NO.: 2:14-cv-02562-MMD-NJK **ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD.**

Defendants, Dr. Reddy's Laboratories, Inc. ("DRL, Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL, Ltd.") (collectively, "Defendants" or "DRL"), for their Answer, Affirmative Defenses, and Counterclaims to Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals

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Ireland Limited's (collectively, "Plaintiffs" or "Amarin") Complaint for Patent Infringement ("Complaint"), state as follows:

NATURE OF THE ACTION

1. DRL admits that the Complaint purports to be an action for patent infringement for the fourteen patents listed in paragraph 1 of the Complaint relating to DRL's ANDA No. 209499, which seeks FDA approval to market DRL's proposed Icosapent Ethyl Capsules. DRL admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). DRL denies all other allegations contained in paragraph 1 of the Complaint.

THE PARTIES

2. DRL admits, on information and belief, that Amarin Pharma, Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at 1430 Route 206, Bedminster, NJ 07921.

3. DRL admits, on information and belief, that Amarin Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

4. DRL admits the allegations in paragraph 4 of the Complaint.

5. DRL admits the allegations in paragraph 5 of the Complaint.

6. DRL admits the allegations in paragraph 6 of the Complaint.

7. DRL admits that it sells generic drug products throughout the United States, including in this judicial district. DRL denies all other allegations contained in paragraph 7 of the Complaint.

8. DRL admits that DRL, Inc. sells generic drug products throughout the United States, including in this judicial district. DRL denies all other allegations contained in paragraph 8 of the Complaint.

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JURISDICTION AND VENUE

9. DRL admits that the Complaint purports to be a civil action for patent infringement arising under United States patent laws for the fourteen patents listed in paragraph 9 of the Complaint. DRL denies all other allegations contained in paragraph 9 of the Complaint.

10. DRL admits the allegations in paragraph 10 of the Complaint.

11. DRL admits that it filed ANDA No. 209499. DRL's ANDA speaks for itself as to its contents. DRL denies all other allegations contained in paragraph 11 of the Complaint.

12. The allegations in paragraph 12 of the Complaint appear to be directed to the question regarding whether this Court has personal jurisdiction over DRL. DRL will not contest personal jurisdiction in the District of Nevada for the purposes of this action only. DRL denies all other allegations contained in paragraph 12 of the Complaint.

13. The allegations in paragraph 13 of the Complaint appear to be directed to the question regarding whether this Court has personal jurisdiction over DRL. DRL will not contest personal jurisdiction in the District of Nevada for the purposes of this action only. DRL denies all other allegations contained in paragraph 13 of the Complaint.

14. The allegations in paragraph 14 of the Complaint appear to be directed to the question regarding whether this Court has personal jurisdiction over DRL. DRL will not contest personal jurisdiction in the District of Nevada for the purposes of this action only. DRL denies all other allegations contained in paragraph 14 of the Complaint.

15. DRL admits that it filed ANDA No. 209499 seeking approval from the FDA to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. Because DRL's future business decisions and activities are uncertain at this time, DRL denies all other allegations contained in paragraph 15 of the Complaint.

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16. Paragraph 16 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is required, DRL states that it does not contest personal jurisdiction in this Court for purposes of this action only. DRL denies all other allegations contained in paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is required, DRL states that it does not contest personal jurisdiction in this Court for purposes of this action only. DRL denies all other allegations contained in paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is required, DRL states that it does not contest venue in this Court for purposes of this action only. DRL admits that this case has been consolidated with *Amarin Pharma Inc. v. Roxane Labs., Inc.*, 2:16-cv-02525-MMD-NJK, which was filed in the District of Nevada on October 31, 2016. DRL denies all other allegations contained in paragraph 18 of the Complaint.

REGULATORY REQUIREMENTS FOR NEW AND GENERIC DRUGS

19. Paragraph 19 of the Complaint sets forth conclusions of law to which no response is required. To the extent a response is required, DRL respectfully refers the Court to 21 U.S.C. § 355(b) for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 19 of the Complaint.

20. Paragraph 20 of the Complaint sets forth conclusions of law to which no response is required. To the extent a response is required, DRL respectfully refers the Court to 21 U.S.C. § 355(j) for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 20 of the Complaint.

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21. Paragraph 21 of the Complaint sets forth conclusions of law to which no response is required. To the extent a response is required, DRL respectfully refers the Court to 21 U.S.C. § 355(j) for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 21 of the Complaint.

22. Paragraph 22 of the Complaint sets forth conclusions of law to which no response is required. To the extent a response is required, DRL respectfully refers the Court to 21 U.S.C. § 355(j) for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 22 of the Complaint.

THE APPROVED DRUG PRODUCT

23. Upon information and belief, DRL admits that the FDA approved NDA No. 202057 on July 26, 2012 and that Amarin Pharmaceuticals Ireland Limited is listed as the applicant for that NDA. DRL further admits that VASCEPA® is a trade name for Amarin's drug product covered by NDA No. 202057. DRL is without sufficient knowledge to admit or deny the remaining allegations in paragraph 23 and, therefore, denies the same.

24. DRL admits that Exhibit A to the Complaint purports to be a copy of the Full Prescribing Information and Patient Information for VASCEPA®. DRL states that Exhibit A speaks for itself and respectfully refers the Court to that document for its true and complete contents. DRL denies all other allegations contained in paragraph 24 of the Complaint.

25. DRL admits that, upon information and belief, Amarin caused the FDA to list the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 patents, among others, in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with NDA No. 202057. DRL denies all other allegations contained in paragraph 25 of the Complaint.

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26. DRL is without sufficient knowledge to admit or deny the allegations in paragraph 26 and, therefore, denies all allegations contained in paragraph 26 of the Complaint.

ANDA No. 209499

27. DRL admits that it filed ANDA No. 209499 with the FDA seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499 for the true and complete contents therein. DRL denies all other allegations contained in paragraph 27 of the Complaint.

28. DRL admits that its proposed labeling submitted in its ANDA complies with the requirements of the Hatch-Waxman Act. DRL refers to its ANDA No. 209499 for the true and complete contents therein. DRL denies all other allegations contained in paragraph 28 of the Complaint.

29. DRL admits that by letter dated September 22, 2016 (DRL's "Notice Letter"), DRL notified Amarin of its ANDA certification that the claims of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 patents, among others, are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 29 of the Complaint.

30. DRL admits that it filed ANDA No. 209499 with the FDA seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 30 of the Complaint.

31. Denied.

COUNT I: PATENT INFRINGEMENT OF THE '728 PATENT

32. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-31 of the Complaint above, as if fully set forth herein.

33. DRL admits that the face page of United States Patent No. 8,293,728 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on October 23, 2012, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '728 patent is attached to the Complaint as Exhibit B. DRL denies all other allegations contained in paragraph 33 of the Complaint.

34. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 34 of the Complaint.

35. Denied.

36. Denied.

37. Denied.

38. DRL admits that its ANDA included a written certification to FDA that the claims of the '728 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 38 of the Complaint.

39. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '728 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 39 of the Complaint.

40. Denied.

41. Denied.

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COUNT II: PATENT INFRINGEMENT OF THE '715 PATENT

42. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-41 of the Complaint above, as if fully set forth herein.

43. DRL admits that the face page of United States Patent No. 8,318,715 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on November 27, 2012, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '715 patent along with the certificate of correction is attached to the Complaint as Exhibit C. DRL denies all other allegations contained in paragraph 43 of the Complaint.

44. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 44 of the Complaint.

45. Denied.

46. Denied.

47. Denied.

48. DRL admits that its ANDA included a written certification to FDA that the claims of the '715 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 48 of the Complaint.

49. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '715 patent are invalid, unenforceable, and/or will not be

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infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 49 of the Complaint.

50. Denied.

51. Denied.

COUNT III: PATENT INFRINGEMENT OF THE '677 PATENT

52. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-51 of the Complaint above, as if fully set forth herein.

53. DRL admits that the face page of United States Patent No. 8,357,677 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on January 22, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '677 patent is attached to the Complaint as Exhibit D. DRL denies all other allegations contained in paragraph 53 of the Complaint.

54. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 54 of the Complaint.

55. Denied.

56. Denied.

57. Denied.

58. DRL admits that its ANDA included a written certification to FDA that the claims of the '677 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 58 of the Complaint.

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59. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '677 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 59 of the Complaint.

60. Denied.

61. Denied.

COUNT IV: PATENT INFRINGEMENT OF THE '652 PATENT

62. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-61 of the Complaint above, as if fully set forth herein.

63. DRL admits that the face page of United States Patent No. 8,367,652 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on February 5, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '652 patent is attached to the Complaint as Exhibit E. DRL denies all other allegations contained in paragraph 63 of the Complaint.

64. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL respectfully refers the Court to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 64 of the Complaint.

65. Denied.

66. Denied.

67. Denied.

68. DRL admits that its ANDA included a written certification to FDA that the claims of the '728 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product.

DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 68 of the Complaint.

69. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '652 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 69 of the Complaint.

70. Denied.

71. Denied.

COUNT V: PATENT INFRINGEMENT OF THE '920 PATENT

72. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-71 of the Complaint above, as if fully set forth herein.

73. DRL admits that the face page of United States Patent No. 8,377,920 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on February 19, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '920 patent is attached to the Complaint as Exhibit F. DRL denies all other allegations contained in paragraph 73 of the Complaint.

74. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 74 of the Complaint.

75. Denied.

76. Denied.

77. Denied.

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78. DRL admits that its ANDA included a written certification to FDA that the claims of the '920 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499 including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 78 of the Complaint.

79. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '920 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 79 of the Complaint.

80. Denied.

81. Denied.

COUNT VI: PATENT INFRINGEMENT OF THE '446 PATENT

82. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-81 of the Complaint above, as if fully set forth herein.

83. DRL admits that the face page of United States Patent No. 8,399,446 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on March 19, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '446 patent is attached to the Complaint as Exhibit G. DRL denies all other allegations contained in paragraph 83 of the Complaint.

84. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 84 of the Complaint.

85. Denied.

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86. Denied.

87. Denied.

88. DRL admits that its ANDA included a written certification to FDA that the claims of the '446 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499 including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 88 of the Complaint.

89. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '446 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 89 of the Complaint.

90. Denied.

91. Denied.

COUNT VII: PATENT INFRINGEMENT OF THE '335 PATENT

92. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-91 of the Complaint above, as if fully set forth herein.

93. DRL admits that the face page of United States Patent No. 8,415,335 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on April 9, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '335 patent is attached to the Complaint as Exhibit H. DRL denies all other allegations contained in paragraph 93 of the Complaint.

94. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to

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its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 94 of the Complaint.

95. Denied.

96. Denied.

97. Denied.

98. DRL admits that its ANDA included a written certification to FDA that the claims of the '335 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 98 of the Complaint.

99. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '335 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 99 of the Complaint.

100. Denied.

101. Denied.

COUNT VIII: PATENT INFRINGEMENT OF THE '399 PATENT

102. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-101 of the Complaint above, as if fully set forth herein.

103. DRL admits that the face page of United States Patent No. 8,426,399 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on April 23, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '399 patent along with the certificate of correction is attached to the

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Complaint as Exhibit I. DRL denies all other allegations contained in paragraph 103 of the Complaint.

104. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 104 of the Complaint.

105. Denied.

106. Denied.

107. Denied.

108. DRL admits that its ANDA included a written certification to FDA that the claims of the '399 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 108 of the Complaint.

109. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '399 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 109 of the Complaint.

110. Denied.

111. Denied.

COUNT IX: PATENT INFRINGEMENT OF THE '560 PATENT

112. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-111 of the Complaint above, as if fully set forth herein.

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113. DRL admits that the face page of United States Patent No. 8,431,560 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on April 30, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '560 patent is attached to the Complaint as Exhibit J. DRL denies all other allegations contained in paragraph 113 of the Complaint.

114. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 114 of the Complaint.

115. Denied.

116. Denied.

117. Denied.

118. DRL admits that its ANDA included a written certification to FDA that the claims of the '560 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 118 of the Complaint.

119. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '560 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA. DRL denies all other allegations contained in paragraph 119 of the Complaint.

120. Denied.

121. Denied.

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COUNT X: PATENT INFRINGEMENT OF THE '650 PATENT

122. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-121 of the Complaint above, as if fully set forth herein.

123. DRL admits that the face page of United States Patent No. 8,440,650 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on May 14, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '650 patent is attached to the Complaint as Exhibit K. DRL denies all other allegations contained in paragraph 123 of the Complaint.

124. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents. DRL denies all other allegations contained in paragraph 124 of the Complaint.

125. Denied.

126. Denied.

127. Denied.

128. DRL admits that its ANDA included a written certification to FDA that the claims of the '650 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 128 of the Complaint.

129. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '650 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 129 of the Complaint.

130. Denied.

131. Denied.

COUNT XI: PATENT INFRINGEMENT OF THE '929 PATENT

132. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-131 of the Complaint above, as if fully set forth herein.

133. DRL admits that the face page of United States Patent No. 8,518,929 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on August 27, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '929 patent is attached to the Complaint as Exhibit L. DRL denies all other allegations contained in paragraph 133 of the Complaint.

134. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 134 of the Complaint.

135. Denied.

136. Denied.

137. Denied.

138. DRL admits that its ANDA included a written certification to FDA that the claims of the '929 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 138 of the Complaint.

139. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '929 patent are invalid, unenforceable, and/or will not be

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infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 139 of the Complaint.

140. Denied.

141. Denied.

COUNT XII: PATENT INFRINGEMENT OF THE '698 PATENT

142. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-141 of the Complaint above, as if fully set forth herein.

143. DRL admits that the face page of United States Patent No. 8,524,698 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on September 3, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '698 patent along with the certificate of correction is attached to the Complaint as Exhibit M. DRL denies all other allegations contained in paragraph 143 of the Complaint.

144. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 144 of the Complaint.

145. Denied.

146. Denied.

147. Denied.

148. DRL admits that its ANDA included a written certification to FDA that the claims of the '698 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and

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complete contents thereof. DRL denies all other allegations contained in paragraph 148 of the Complaint.

149. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '698 patent are invalid, unenforceable, and/or will not be infringed by DRL. DRL denies all other allegations contained in paragraph 149 of the Complaint.

150. Denied.

151. Denied.

COUNT XIII: PATENT INFRINGEMENT OF THE '372 PATENT

152. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-151 of the Complaint above, as if fully set forth herein.

153. DRL admits that the face page of United States Patent No. 8,546,372 indicates it is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," issued on October 1, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '372 patent is attached to the Complaint as Exhibit N. DRL denies all other allegations contained in paragraph 153 of the Complaint.

154. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 154 of the Complaint.

155. Denied.

156. Denied.

157. Denied.

158. DRL admits that its ANDA included a written certification to FDA that the claims of the '372 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product.

DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 158 of the Complaint.

159. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '372 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 159 of the Complaint.

160. Denied.

161. Denied.

COUNT XIV: PATENT INFRINGEMENT OF THE '594 PATENT

162. DRL repeats, reasserts, and incorporates by reference its answers to paragraphs 1-161 of the Complaint above, as if fully set forth herein.

163. DRL admits that the face page of United States Patent No. 8,617,594 indicates it is entitled "STABLE PHARMACEUTICAL COMPOSITION AND METHODS OF USING SAME," issued on December 31, 2013, and lists Amarin Pharmaceuticals Ireland Limited as assignee. DRL further admits that what purports to be a copy of the '594 patent is attached to the Complaint as Exhibit O. DRL denies all other allegations contained in paragraph 163 of the Complaint.

164. DRL admits that it filed ANDA No. 209499 with the FDA, seeking approval to manufacture and sell DRL's proposed Icosapent Ethyl Capsule described therein. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 164 of the Complaint.

165. Denied.

166. Denied.

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167. Denied.

168. DRL admits that its ANDA included a written certification to FDA that the claims of the '594 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL refers to its ANDA No. 209499, including its paragraph IV certification, for the true and complete contents thereof. DRL denies all other allegations contained in paragraph 168 of the Complaint.

169. DRL admits that by letter dated September 22, 2016, DRL notified Amarin of its ANDA certification that the claims of the '594 patent are invalid, unenforceable, and/or will not be infringed by DRL's ANDA product. DRL denies all other allegations contained in paragraph 169 of the Complaint.

170. Denied.

171. Denied.

ANSWER TO PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to the judgment or other relief prayed for in Paragraphs A-G under the heading "Prayer for Relief" in the Complaint.

AFFIRMATIVE DEFENSES

Without prejudice to the admissions and denials set forth in its Answer, DRL asserts the following Affirmative Defenses to Amarin's Complaint. DRL does not assume the burden of proof with respect to those matters that, under law, Amarin bears the burden of proof. DRL reserves the right to assert other defenses and/or to otherwise supplement or amend its Answer and Affirmative Defenses to the Complaint under discovery of facts or evidence rendering such action appropriate.

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FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,293,728)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,293,728 ("the '728 patent") either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,293,728)

The claims of the '728 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,318,715)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,318,715 ("the '715 patent") either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,318,715)

The claims of the '715 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102

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because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,357,677)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,357,677 ("the '677 patent") either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,357,677)

The claims of the '677 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,367,652)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule product that is the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,367,652 ("the '652 patent") either literally or under the doctrine of equivalents.

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EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,367,652)

The claims of the '652 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,377,920)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,377,920 ("the '920 patent") either literally or under the doctrine of equivalents.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,377,920)

The claims of the '920 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

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ELEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,399,446)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,399,446 ("the '446 patent") either literally or under the doctrine of equivalents.

TWELFTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,399,446)

The claims of the '446 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

THIRTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,415,335)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,415,335 ("the '335 patent") either literally or under the doctrine of equivalents.

FOURTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,415,335)

The claims of the '335 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102

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because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

FIFTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,426,399)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,426,399 ("the '399 patent") either literally or under the doctrine of equivalents.

SIXTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,426,399)

The claims of the '399 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,431,560)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,431,560 ("the '560 patent") either literally or under the doctrine of equivalents.

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EIGHTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,431,560)

The claims of the '560 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

NINETEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,440,650)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,440,650 ("the '650 patent") either literally or under the doctrine of equivalents.

TWENTIETH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,440,650)

The claims of the '650 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

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TWENTY-FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,518,929)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,518,929 ("the '929 patent") either literally or under the doctrine of equivalents.

TWENTY-SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,518,929)

The claims of the '929 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

TWENTY-THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,524,698)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,524,698 ("the '698 patent") either literally or under the doctrine of equivalents.

TWENTY-FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,524,698)

The claims of the '698 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102

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because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

TWENTY-FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,546,372)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,546,372 ("the '372 patent") either literally or under the doctrine of equivalents.

TWENTY-SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,546,372)

The claims of the '372 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,617,594)

The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,617,594 ("the '594 patent") either literally or under the doctrine of equivalents.

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TWENTY-EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,617,594)

The claims of the '594 patent are invalid under 35 U.S.C. § 101 because the alleged inventions claimed therein cover naturally-occurring phenomena; invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by the prior art; invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art; and invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite.

TWENTY-NINTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Amarin fails to allege sufficient facts to state any claim for which relief can be granted.

THIRTIETH AFFIRMATIVE DEFENSE

DRL adopts and incorporates by reference any affirmative defense of any other Defendants joined or consolidated as parties with this action as may be applicable to DRL.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Counterclaim Plaintiffs, Dr. Reddy's Laboratories, Inc. ("DRL, Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL, Ltd.") (collectively, "DRL"), for their Counterclaims against Counterclaim Defendants Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively, "Counterclaim Defendants" or "Amarin") allege and aver as follows:

1. Counterclaimant DRL, Inc. is a corporation organized under the laws of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

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2. Counterclaimant DRL, Ltd. is an Indian public limited liability company incorporated and existing under the laws of India and having a principal place of business at 8-2-337, Road no. 3, Banjara Hills, Hyderabad, Andhra Pradesh, 500 034, India.

3. Upon information and belief, Plaintiff and Counterclaim Defendant Amarin Pharma, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 1430 Route 206, Bedminster, New Jersey 07921.

4. Upon information and belief, Plaintiff and Counterclaim Defendant Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

5. As a consequence of Amarin's Complaint against DRL, there is an existing, continuing, actual controversy between Amarin and DRL regarding the alleged infringement and validity of United States Patent No. 8,293,728 ("the '728 patent"), U.S. Patent No. 8,318,715 ("the '715 patent"), U.S. Patent No. 8,357,677 ("the '677 patent"), U.S. Patent No. 8,367,652 ("the '652 patent"), U.S. Patent No. 8,377,920 ("the '920 patent"), U.S. Patent No. 8,399,446 ("the '446 patent"), U.S. Patent No. 8,415,335 ("the '335 patent"), U.S. Patent No. 8,426,399 ("the '399 patent"), U.S. Patent No. 8,431,560 ("the '560 patent"), U.S. Patent No. 8,440,650 ("the '650 patent"), U.S. Patent No. 8,518,929 ("the '929 patent"), U.S. Patent No. 8,524,698 ("the '698 patent"), U.S. Patent No. 8,546,372 ("the '372 patent"), and U.S. Patent No. 8,617,594 ("the '594 patent") (collectively, "the patents-in-suit").

6. This Court has jurisdiction over the subject matter of these counterclaims pursuant to §§ 1331 and 1338(a) of Title 28 of the United States Code, as they involve claims arising out of the United States Patent Act, 35 U.S.C. § 1, *et seq*.

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7. This Court may declare the rights and legal relations for the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5) because DRL's Counterclaims present an actual controversy within the Court's jurisdiction.

8. Venue for these Counterclaims is proper in this District in which Amarin's Complaint is pending.

COUNT 1
Declaratory Judgment of Noninfringement of the '728 Patent

9. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-8, as if fully set forth herein.

10. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,293,728 ("the '728 patent") either literally or under the doctrine of equivalents.

COUNT 2
Declaratory Judgment of Invalidity of the '728 Patent

11. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-10, as if fully set forth herein.

12. Upon information and belief, the claims of the '728 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

13. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '728 patent.

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14. At the earliest priority date of the '728 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

15. Upon information and belief, the claims of the '728 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '728 patent are found, either expressly or inherently described, in WO '118.

16. Upon information and belief, the claims of the '728 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

17. Upon information and belief, the claims of the '728 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '728 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 3
Declaratory Judgment of Noninfringement of the '715 Patent

18. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-17, as if fully set forth herein.

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19. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,318,715 ("the '715 patent") either literally or under the doctrine of equivalents.

COUNT 4
Declaratory Judgment of Invalidity of the '715 Patent

20. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-19, as if fully set forth herein.

21. Upon information and belief, the claims of the '715 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

22. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '715 patent.

23. At the earliest priority date of the '715 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

24. Upon information and belief, the claims of the '715 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO

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'118"). Each and every element set forth in the claims of the '715 patent are found, either expressly or inherently described, in WO '118.

25. Upon information and belief, the claims of the '715 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

26. Upon information and belief, the claims of the '715 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '715 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 5
Declaratory Judgment of Noninfringement of the '677 Patent

27. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-26, as if fully set forth herein.

28. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,357,677 ("the '677 patent") either literally or under the doctrine of equivalents.

COUNT 6
Declaratory Judgment of Invalidity of the '677 Patent

29. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-28, as if fully set forth herein.

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30. Upon information and belief, the claims of the '677 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

31. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '677 patent.

32. At the earliest priority date of the '677 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

33. Upon information and belief, the claims of the '677 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '677 patent are found, either expressly or inherently described, in WO '118.

34. Upon information and belief, the claims of the '677 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

35. Upon information and belief, the claims of the '677 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '677 patent does not adequately describe or enable the meaning or scope of

certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 7
Declaratory Judgment of Noninfringement of the '652 Patent

36. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-35, as if fully set forth herein.

37. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,367,652 ("the '652 patent") either literally or under the doctrine of equivalents.

COUNT 8
Declaratory Judgment of Invalidity of the '652 Patent

38. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-37, as if fully set forth herein.

39. Upon information and belief, the claims of the '652 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

40. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '652 patent.

41. At the earliest priority date of the '652 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing

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ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

42. Upon information and belief, the claims of the '652 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '652 patent are found, either expressly or inherently described, in WO '118.

43. Upon information and belief, the claims of the '652 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

44. Upon information and belief, the claims of the '652 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '652 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 9
Declaratory Judgment of Noninfringement of the '920 Patent

45. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-44, as if fully set forth herein.

46. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly

construed claim of U.S. Patent No. 8,377,920 ("the '920 patent") either literally or under the doctrine of equivalents.

COUNT 10
Declaratory Judgment of Invalidity of the '920 Patent

47. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-46, as if fully set forth herein.

48. Upon information and belief, the claims of the '920 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

49. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '920 patent.

50. At the earliest priority date of the '920 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

51. Upon information and belief, the claims of the '920 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '920 patent are found, either expressly or inherently described, in WO '118.

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52. Upon information and belief, the claims of the '920 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

53. Upon information and belief, the claims of the '920 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '920 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison to a baseline.

COUNT 11
Declaratory Judgment of Noninfringement of the '446 Patent

54. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-53, as if fully set forth herein.

55. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,399,446 ("the '446 patent") either literally or under the doctrine of equivalents.

COUNT 12
Declaratory Judgment of Invalidity of the '446 Patent

56. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-55, as if fully set forth herein.

57. Upon information and belief, the claims of the '446 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of "administering . . . ethyl eicosapentaenoate," a known naturally-

occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

58. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '446 patent.

59. At the earliest priority date of the '446 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

60. Upon information and belief, the claims of the '446 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '446 patent are found, either expressly or inherently described, in WO '118.

61. Upon information and belief, the claims of the '446 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

62. Upon information and belief, the claims of the '446 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '446 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

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COUNT 13
Declaratory Judgment of Noninfringement of the '335 Patent

63. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-62, as if fully set forth herein.

64. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,415,335 ("the '335 patent") either literally or under the doctrine of equivalents.

COUNT 14
Declaratory Judgment of Invalidity of the '335 Patent

65. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-64, as if fully set forth herein.

66. Upon information and belief, the claims of the '335 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

67. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '335 patent.

68. At the earliest priority date of the '335 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred

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to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

69. Upon information and belief, the claims of the '335 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '335 patent are found, either expressly or inherently described, in WO '118.

70. Upon information and belief, the claims of the '335 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

71. Upon information and belief, the claims of the '335 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '335 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 15
Declaratory Judgment of Noninfringement of the '399 Patent

72. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-71, as if fully set forth herein.

73. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,426,399 ("the '399 patent") either literally or under the doctrine of equivalents.

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COUNT 16
Declaratory Judgment of Invalidity of the '399 Patent

74. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-73, as if fully set forth herein.

75. Upon information and belief, the claims of the '399 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

76. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '399 patent.

77. At the earliest priority date of the '399 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

78. Upon information and belief, the claims of the '399 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '399 patent are found, either expressly or inherently described, in WO '118.

79. Upon information and belief, the claims of the '399 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

80. Upon information and belief, the claims of the '399 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '399 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 17
Declaratory Judgment of Noninfringement of the '560 Patent

81. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-80, as if fully set forth herein.

82. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,431,560 ("the '560 patent") either literally or under the doctrine of equivalents.

COUNT 18
Declaratory Judgment of Invalidity of the '560 Patent

83. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-82, as if fully set forth herein.

84. Upon information and belief, the claims of the '560 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of "administering . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

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85. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '560 patent.

86. At the earliest priority date of the '560 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

87. Upon information and belief, the claims of the '560 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '560 patent are found, either expressly or inherently described, in WO '118.

88. Upon information and belief, the claims of the '560 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

89. Upon information and belief, the claims of the '560 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '560 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

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COUNT 19
Declaratory Judgment of Noninfringement of the '650 Patent

90. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-89, as if fully set forth herein.

91. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,440,650 ("the '650 patent") either literally or under the doctrine of equivalents.

COUNT 20
Declaratory Judgment of Invalidity of the '650 Patent

92. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-91, as if fully set forth herein.

93. Upon information and belief, the claims of the '650 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

94. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '650 patent.

95. At the earliest priority date of the '650 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred

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to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

96. Upon information and belief, the claims of the '650 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '650 patent are found, either expressly or inherently described, in WO '118.

97. Upon information and belief, the claims of the '650 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

98. Upon information and belief, the claims of the '650 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '650 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

COUNT 21
Declaratory Judgment of Noninfringement of the '929 Patent

99. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-98, as if fully set forth herein.

100. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,518,929 ("the '929 patent") either literally or under the doctrine of equivalents.

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COUNT 22
Declaratory Judgment of Invalidity of the '929 Patent

101. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-100, as if fully set forth herein.

102. Upon information and belief, the claims of the '929 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

103. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '929 patent.

104. At the earliest priority date of the '929 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

105. Upon information and belief, the claims of the '929 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '929 patent are found, either expressly or inherently described, in WO '118.

106. Upon information and belief, the claims of the '929 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

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107. Upon information and belief, the claims of the '929 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '929 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, and the dosages and quantities that may provide a benefit.

COUNT 23
Declaratory Judgment of Noninfringement of the '698 Patent

108. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-107, as if fully set forth herein.

109. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,524,698 ("the '698 patent") either literally or under the doctrine of equivalents.

COUNT 24
Declaratory Judgment of Invalidity of the '698 Patent

110. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-109, as if fully set forth herein.

111. Upon information and belief, the claims of the '698 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of administering "a pharmaceutical composition comprising . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

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112. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '698 patent.

113. At the earliest priority date of the '698 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

114. Upon information and belief, the claims of the '698 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '698 patent are found, either expressly or inherently described, in WO '118.

115. Upon information and belief, the claims of the '698 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

116. Upon information and belief, the claims of the '698 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '698 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and the comparison of patient or subject groups.

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COUNT 25
Declaratory Judgment of Noninfringement of the '372 Patent

117. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-116, as if fully set forth herein.

118. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,546,372 ("the '372 patent") either literally or under the doctrine of equivalents.

COUNT 26
Declaratory Judgment of Invalidity of the '372 Patent

119. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-118, as if fully set forth herein.

120. Upon information and belief, the claims of the '372 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of "administering . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

121. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '372 patent.

122. At the earliest priority date of the '372 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred

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to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

123. Upon information and belief, the claims of the '372 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '372 patent are found, either expressly or inherently described, in WO '118.

124. Upon information and belief, the claims of the '372 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

125. Upon information and belief, the claims of the '372 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '372 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amounts of ethyl EPA and DHA in the composition, the dosages and quantities that may provide a benefit, and how a group of subjects should be identified.

COUNT 27
Declaratory Judgment of Noninfringement of the '594 Patent

126. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-125, as if fully set forth herein.

127. The manufacture, use, sale, offer to sell, or importation into the United States of DRL's proposed Icosapent Ethyl Capsule products that are the subject of ANDA No. 209499 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,617,594 ("the '594 patent") either literally or under the doctrine of equivalents.

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COUNT 28
Declaratory Judgment of Invalidity of the '594 Patent

128. DRL repeats, reasserts, and incorporates by reference the allegations set forth in paragraphs 1-127, as if fully set forth herein.

129. Upon information and belief, the claims of the '594 patent are invalid under 35 U.S.C. §101 because the claims cover naturally-occurring phenomena. Each of the claimed methods is to be effected by means of "administering . . . ethyl eicosapentaenoate," a known naturally-occurring compound. The claimed effects are the natural result of ingesting a naturally-occurring substance.

130. DRL attaches hereto a listing of references (Exhibit A), which DRL incorporates by reference herein, and which, upon information and belief, constitute prior art to the '594 patent.

131. At the earliest priority date of the '594 patent, ethyl eicosapentaenoate ("ethyl EPA") and docosahexaenoic acid (DHA) were known to lower triglycerides, and dosage forms containing ethyl EPA and DHA had been approved in various countries around the world. Highly-purified ethyl EPA and pharmaceutical compositions comprising the same were also known. It was further known that DHA had the adverse effect of increasing LDL-C, which is commonly referred to as bad cholesterol. Accordingly, it was known to administer highly-purified ethyl EPA to lower triglycerides.

132. Upon information and belief, the claims of the '594 patent are invalid under 35 U.S.C. § 102 because the alleged inventions claimed therein are anticipated by WO 2007/142118 ("WO '118"). Each and every element set forth in the claims of the '594 patent are found, either expressly or inherently described, in WO '118.

133. Upon information and belief, the claims of the '594 patent are invalid under 35 U.S.C. § 103 because the alleged inventions claimed therein are obvious to one having ordinary skill in the art in view of the prior art, including but not limited to the prior art listed in Exhibit A.

134. Upon information and belief, the claims of the '594 patent are invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, and because the claims are indefinite. Specifically, the '594 patent does not adequately describe or enable the meaning or scope of certain limitations of the claims, including but not limited to, limitations directed to the claimed required results, the actual amount of ethyl EPA in the composition, the dosages and quantities that may provide a benefit, and how a group of subjects should be identified.

DRL'S PRAYER FOR RELIEF

WHEREFORE, DRL respectfully requests that the Court enter judgment against Plaintiffs as follows:

A. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,293,728, either literally or under the doctrine of equivalents;

B. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,318,715, either literally or under the doctrine of equivalents;

C. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,357,677, either literally or under the doctrine of equivalents;

D. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,367,652, either literally or under the doctrine of equivalents;

E. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,377,920, either literally or under the doctrine of equivalents;

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F. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,399,446, either literally or under the doctrine of equivalents;

G. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,415,335, either literally or under the doctrine of equivalents;

H. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,426,399, either literally or under the doctrine of equivalents;

I. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,431,560, either literally or under the doctrine of equivalents;

J. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,440,650, either literally or under the doctrine of equivalents;

K. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,518,929, either literally or under the doctrine of equivalents;

L. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,524,698, either literally or under the doctrine of equivalents;

M. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,546,372, either literally or under the doctrine of equivalents;

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N. Declaring that DRL would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No. 8,617,594, either literally or under the doctrine of equivalents;

O. Declaring that the patent claims in United States Patent No. 8,293,728 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

P. Declaring that the patent claims in United States Patent No. 8,318,715 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

Q. Declaring that the patent claims in United States Patent No. 8,357,677 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

R. Declaring that the patent claims in United States Patent No. 8,367,652 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

S. Declaring that the patent claims in United States Patent No. 8,377,920 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

T. Declaring that the patent claims in United States Patent No. 8,399,446 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

U. Declaring that the patent claims in United States Patent No. 8,415,335 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

V. Declaring that the patent claims in United States Patent No. 8,426,399 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

W. Declaring that the patent claims in United States Patent No. 8,431,560 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

X. Declaring that the patent claims in United States Patent No. 8,440,650 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

Y. Declaring that the patent claims in United States Patent No. 8,518,929 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

Z. Declaring that the patent claims in United States Patent No. 8,524,698 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

AA. Declaring that the patent claims in United States Patent No. 8,546,372 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

BB. Declaring that the patent claims in United States Patent No. 8,617,594 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

CC. Awarding DRL its reasonable costs and attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

DD. Such further and other relief as this Court may deem just and proper.

DATED: January 13, 2017

Respectfully submitted,

By: /s/ *Michael D. Rounds*

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CERTIFICATE OF SERVICE

Pursuant to FRCP 5(b), I certify that I am an employee of BROWNSTEIN HYATT FARBER SCHRECK, LLP, and on this 13th day of January, 2017, I served the document entitled **ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD.**, on the parties listed below via the following:

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☐ **VIA FIRST CLASS U.S. MAIL:** by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail at Reno, Nevada for delivery to the foregoing.

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/s/ Jeff Tillison
Employee of Brownstein Hyatt Farber Schreck, LLP